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09/597,608 06/20/00 NGAI

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RICHARD ARON OSMAN
SCIENCE AND TECHNOLOGY LAW GROUP
75 DENISE DRIVE
HILLSBOROUGH CA 94010

EXAMINER

TAYLOR, J	
ART UNIT	PAPER NUMBER

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 14

Application Number: 09/597,608
Filing Date: June 20, 2000
Appellant(s): NGAI ET AL.

Richard Aron Osman, Ph.D.
For Appellant

EXAMINER'S ANSWER

(1) ***Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

(2) ***Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) ***Status of Claims***

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 19 and 20 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,114,152	SERAFINI et al.	9-2000
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5,591,575	HAMPSON et al.	7-1997
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Stratagene Catalog, 1995, page 109.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Catalog, 1995, page 109.

The claim is drawn to a kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1, and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides.

Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Stratagene. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art.

Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers and buffer, and instructions, among other things. Therefore, all of the limitations of the instant claim are anticipated by Stratagene.

Claim Rejections - 35 USC § 103

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stratagene in view of Serafini et al. in view of Hampson et al. (USPN 5,591,575).

Claim 20 depends from claim 19, and comprises premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides.

Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers, buffer, and instructions (page 161).

Stratagene does not teach the use of biotinylated primers and streptavidin beads, or polyadenyl transferase, or DNA pol I.

Serafini et al. teach polyadenyltransferase and DNA polymerase (Cols. 3-4).

Hampson et al. teach biotinylated primer and streptavidin beads (claim 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the kit of Stratagene by adding biotinylated primers and streptavidin beads, as well as polyadenyl transferase and DNA pol I. This is because biotinylated primers and streptavidin beads would have been very effective in capturing and identifying an amplified nucleic acid. It would also have been obvious to add polyadenyl

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transferase and DNA pol I because polyadenyl transferase was useful for adding poly(A) sequence, and DNA polymerase was necessary for amplification. All of these items would have been useful in a kit because they would have allowed the practitioner to amplify a sequence, capture, and identify said sequence.

(11) Response to Argument

Arguments

5. Applicant's arguments have been fully considered but they are not persuasive.

First, Applicant asserts that "the term 'patentable weight' is legally meaningless."

However, in the case of *In re Schreiber*, 44 USPQ2d 1429, decided October 23, 1997, the term "patentable weight" is referred to numerous times. It is therefore submitted that the term has legal meaning, which has been recognized by the courts. Secondly, in regards to the reference of *In re Haller*, Applicant states that the citation of this case was improper and does not support the examiner's position. However, *In re Haller* states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. Thirdly, Applicant argues that in *In re Gulack*, the Federal Circuit reversed a Board contention that printed matter could not impart patentability. However, in the case of *In re Gulack*,

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the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional absent the printed instructions for use. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03:

Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the claims are drawn to a kit comprising instructions, and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides. The intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

Furthermore, Applicant has submitted that the rejection of claims 19 and 20 was inappropriate because "hundreds of patents issued in the past few years that clearly rely on the printed matter limitation." However, it is not clear from the examples that the instructions are the component being relied upon to impart patentability, and not another component of the kit. For example, in US 6,177,407, a kit is claimed in claim 2, which comprises multiple SEQ ID NOS as well as instructions. It is asserted that in this case, the SEQ ID NOS are what imparts patentability to the claim, and not the instructions.


Lastly, in *in re Miller*, (CCPA 1969) 164 USPQ 46, which has as the disclosed invention a set of measuring devices that contain a set of printed indicia upon them referring to fractionated measurements, as well as a legend to such printing, it is stated that "the fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon indicating volume in a certain ratio to actual volume, and a legend indicating the ratio..." (page 5). This suggests that in order for printed matter to be considered patentable subject matter, there must exist a new and unobvious *functional* relationship between the printed matter and the other elements of the claim. However, in the case of instant claims 19 and 20, no such functional relationship exists. The printed matter merely contains instructions for one use of components of a kit, and no functional relationship exists between the instructions and the other elements of the kit because the components of the kit are capable of functioning without the printed matter.

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For the above reasons, it is believed that the rejections should be sustained.

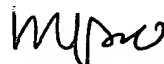
Respectfully submitted,

Janell Taylor Cleveland
Examiner
Art Unit 1655


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

October 3, 2001

RICHARD ARON OSMAN
SCIENCE AND TECHNOLOGY LAW GROUP
75 DENISE DRIVE
HILLSBOROUGH, CA 94010


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
CONFIDENTIAL